K010909

APR - 9 2001

IX. Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical A division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Robert Zott
DATE PREPARED:	March 23, 2001
CLASSIFICATION NAME:	Nonabsorbable Polypropylene Surgical Suture
COMMON NAME:	Modified USS Polypropylene Suture
PROPRIETARY NAME:	To be determined.
PREDICATE DEVICES:	USSC Polypropylene Suture (K954808)
INTENDED USE:	Modified USS Polypropylene Sutures are indicated for use in all types of soft tissue approximation and ligation, including cardiovascular, ophthalmic, microsurgery, and neural tissue.
PERFORMANCE:	The performance of the Modified USS Polypropylene Suture is substantially equivalent to the currently marketed USSC Polypropylene Suture (K954808), which has been successfully used in clinical applications as a wound closure device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Mr. Robert Zott
Associate, Regulatory Affairs
Tyco Healthcare Group, LP
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K010909
Trade Name: Modified USS Polypropylene Suture
Regulatory Class: II
Product Code: GAW
Dated: March 23, 2001
Received: March 26, 2001

Dear Mr. Zott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use

510(k) Number (if known): K010909

Device Name:

Modified USS Polypropylene Suture

Indications For Use:

Modified USS Polypropylene Sutures are indicated for use in all types of soft tissue approximation and ligation, including cardiovascular, ophthalmic, microsurgery, and neural tissue.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use:
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010909